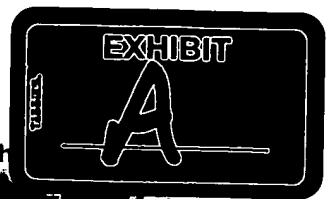




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Vaccines, Immunization and Biologicals

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Vaccine types considered and processes involved

Vaccine type	Process	Summary
Attenuated microbial cells	Growth and purification of microbial cells adapted or engineered to delete pathogenicity, retaining immunogenicity.	Fermentation in defined media; recovery of whole microbial cells by centrifugation/washing or ultrafiltration methods; formulation, filling.
Live microbial vector	Growth and purification of non-pathogenic microbial cells carrying added gene for an immunogenic protein.	Fermentation in defined media; recovery of whole microbial cells by centrifugation/washing or ultrafiltration methodology; formulation, filling.
DNA vaccine	Extraction and purification of plasmid DNA from bacterial cells containing desired gene in the plasmid.	Fermentation in defined media; recovery of whole microbial cells by centrifugation/washing or ultrafiltration methodology; cell lysis and removal of cell debris (filtration, centrifugation or expanded bed chromatography); removal of host impurities, RNA, genomic DNA, proteins and endotoxins (salting out, PEG precipitation); concentration (ultrafiltration methodology, PEG precipitation); purification of plasmid DNA by IEC and/or SEC; concentration and buffer exchange; sterile filtration of final bulk; formulation, filling.
Purified protein, excreted or cell associated	Growth of recombinant bacteria, yeast or cell culture where recombinant protein, cell lysis (for cell associated proteins), isolation and purification of the protein.	Fermentation in defined media; removal of microbial cells by centrifugation or filtration; mechanical disruption of cells, removal of cell debris, solubilization (if necessary); concentration of soluble protein by ultrafiltration methodology; protein purification by chromatography, concentration, buffer exchange, sterile filtration and stabilization; formulation, filling.
Conjugated polysaccharides	Growth of bacterial culture, extraction and purification of capsular polysaccharides, preparation of carrier protein, conjugation to carrier protein.	Fermentation in defined media; primary recovery of cells; isolation/extraction of polysaccharide by chromatography or precipitation; chemical characterization of the polysaccharide; concentration and drying of bulk. Purification of carrier protein (see purification sequence described above). Chemical modification of

		polysaccharide; linker if required; chemical processing of carrier if required; conjugation; separation of conjugated from un-conjugated species by chromatography; concentration of bulk conjugate, sterile filtration and stabilization; formulation; filling.
Live attenuated viruses	Growth of cells (from cell banks of continuous cells or isolation of primary cells), infection with attenuated virus, isolation and purification of virus.	Cell culturing (risk free medium) in bioreactors, roller bottles, hollow fiber, cell cubes, flasks, or microcarrier culture with various types of feeding; virus infection; cell controls; removal of cell or cell debris by centrifugation or ultrafiltration methodology; purification of virus if required, concentration; stabilization, formulation; filling.
Multiple antigen peptide vaccines	Linking of synthetic peptide antigens to a synthetic backbone (eg polylysine).	Peptide synthesis and purification; backbone synthesis and purification; linking of antigens to backbone; purification of multiple antigen peptide product.; sterile filtration; stabilization; formulation; filling.
Virus-like particles	Growth of cells, infection by virus or recombinant virus producing non-replicating, non-infectious, particles with intact immunogenic antigens, isolation and purification of the virus-like particles.	Cell culturing (risk free medium) in bioreactors, roller bottles, hollow fiber, cell cubes, flasks, or microcarrier culture with various types of feeding; virus infection; cell controls; removal of cell or cell debris by centrifugation or ultrafiltration methodology; differential separation of virus-like particle from virus if required, purification and concentration; stabilization; formulation; filling.
Live viral vectors	Growth of cells, infection with genetically engineered replicating non-pathogenic viruses containing added gene of interest, isolation and purification of virus.	Cell culturing (risk free medium) in bioreactors, roller bottles, hollow fiber, cell cubes, flasks, or microcarrier culture with various types of feeding; virus infection; cell controls; removal of cell or cell debris by centrifugation or ultrafiltration methodology; purification of virus if required, concentration; formulation; filling.

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